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RAIZEN, DEBORAH A

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2873	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/894,351	Applicant(s) LEGERTON ET AL.	
	Examiner Deborah A. Raizen	Art Unit 2873	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-44 is/are pending in the application.

4a) Of the above claim(s) 29-44 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6,9-12,15,16,19-22,24,25 and 27 is/are rejected.

7)☒ Claim(s) 7,8,13,14,17,18,23,26 and 28 is/are objected to.

8)☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 27 June 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28, drawn to a contact lens, classified in class 351, subclass 160 R.

II. Claims 29-32, drawn to a method of fitting a contact lens, classified in class 351, subclass 247.

III. Claim 33, drawn to a method of establishing centration, classified in class 351, subclass 177.

IV. Claims 34 and 35, drawn to a method of fitting, adjusting, visualizing, teaching, assessing and communicating a preferred geometry for a contact lens, classified in class 351, subclass 247.

V. Claim 36, drawn to a method of manufacturing a contact lens, classified in class 451, subclass 5.

VI. Claim 37, drawn to a method for altering the shape of a patients cornea, and claim 38, drawn to a method of treating visual acuity deficiencies, classified in class 606, subclass 5.

VII. Claim 39-44, drawn to computer program product, classified in class 451, subclass 5.

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

made by another and materially different process (MPEP § 806.05(f)). In the instant case, the contact lens as claimed in group I can be made without fitting it to a particular patient: for example, contact lenses for fitting sets are made before fitting to a particular patient.

Inventions II and I are also related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method of fitting contact lenses as claimed can be practiced without a fitting set, by corneal topography measurements, such as photokeratoscopy. Also, the contact lens as claimed can be used for corneal refractive therapy (rather than for fitting sets).

3. Inventions III and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the contact lens as claimed can be used for corneal refractive therapy (rather than for establishing centration).

4. Inventions IV and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the contact lens as

claimed can be used for corneal refractive therapy, rather than for fitting ... and communicating a preferred geometry.

5. Inventions IV and I are also related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the contact lens as claimed can be made without reference to a patient, by choosing its parameters independently (for example, to generate fitting sets).

6. Inventions V and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the contact lens as claimed in group I can be made (less accurately) by molding or with a manually operated lathe, without a computer system and without a computerized lathe.

7. Inventions VI and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the contact lens as claimed can be used for fitting, or for establishing centration, or for correcting vision as a conventional contact lens.

8. Inventions VII and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the contact lens as claimed can be made by pencil and paper calculations and by manually operating a lathe or by molding the lens.

9. Inventions VII and I are also related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the contact lens as claimed can be used for establishing centration, for corneal refractive therapy, or for correcting vision, rather than for fitting.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

11. During a telephone conversation with Scott Oldham on July 23, 2003, a provisional election was made with traverse to prosecute the invention of group I, claims 1-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-44 are

withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

13. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in China on 20 October 2000 (application number 00129863.1). It is noted, however, that applicant has not filed a certified copy of the Chinese application as required by 35 U.S.C. 119(b).

Also, the requested amendment to the specification to relate back to the U.S. provisional application, made in paper #1, has not been entered. Please request it again, but write the application number and filing date as part of the sentence, rather than in tabular format.

Specification

14. The abstract of the disclosure is objected to because it has more than 150 words. Correction is required. See MPEP § 608.01(b).

15. The disclosure is objected to because of the following informalities:

On page 6, paragraph [0012], line 3, the abbreviation (HVID) should follow "horizontal visible iris diameter" to make the meaning of the abbreviation clear for subsequent uses.

Appropriate correction is required.

Claim Objections

16. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 depends on claim 5 and is almost identical, except that it does not have the limitation "annular", recited in claim 5, and therefore is broader.

17. Claims 12, 24, and 26 are objected to because of the following informalities:

In claim 12, r_b is not defined.

In claim 24, a bracket is found in line 1.

In claim 26, line 2, the article "an" should precede both the words "ellipse" (there is no antecedent basis for "the", and "a" is not grammatically correct).

Appropriate correction is required.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

19. Claims 1, 2, 4, 10, 12, 15, 16, 20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by El Hage (5,695,509, cited in applicants' IDS, paper #4).

In regard to claim 1, El Hage discloses a corneal contact lens (Fig. 5B) comprising a central zone (10) having a posterior surface curvature (Fig. 5B), a connecting zone (the zone with peaks labeled 12 and 14, also labeled the relief and anchor zones) having a posterior surface (Fig. 5B) and provided adjacent and concentric to said central zone (Figs. 5A and 5B), said connecting zone having a shape defined as a sigmoidal curve (Fig. 5B), and at least one peripheral zone (16) having a posterior surface (Fig. 5B) and provided adjacent and concentric to said connecting zone (Figs. 5A and 5B).

In regard to claim 2, in the El Hage corneal contact lens, the curvature of the central zone is spherical (col. 7, lines 14-18 and 28-30: the disclosure that a shape factor is selected to correspond to the patient's corneal deviation from a perfect sphere inherently discloses the possibility of a spherical central zone because the patient's cornea can be spherical in the center).

In regard to claim 4, in the El Hage corneal contact lens, the curvature of the central zone is aspherical (col. 7, lines 14-18).

In regard to claim 10, in the El Hage corneal contact lens, the meridional profile of the connecting zone is described by its axial length and horizontal width (Fig. 5B: the connecting zone has an axial length and horizontal width; see also MPEP 2113 [R-1, Feb 2003]).

In regard to claim 12, in the El Hage corneal contact lens, the meridional profile of the connecting zone has the shape described by equations 1-8 (Fig. 5B: the connecting zone can be fit to the equations because the equations do not require the slope to match the slope of the central zone).

In regard to claim 15, in the El Hage corneal contact lens, the meridional profile of the at least one peripheral zone is substantially uncurved over at least a substantial portion thereof (Fig. 5B shows that in the region of the peripheral zone where it is labeled 16, it is substantially uncurved).

In regard to claim 16, in the El Hage corneal contact lens, the meridional profile of the at least one peripheral zone is terminated by a rounded shape, to thereby provide smooth edge contour (in Fig. 5B, the edge labeled 18 is rounded).

In regard to claim 20, in the El Hage corneal contact lens, the anterior surface (top in Fig. 5B) of said lens is made to substantially the same shape as the posterior surface of said contact lens (Fig. 5B).

In regard to claim 22, in the El Hage corneal contact lens, the anterior surface of said contact lens is designed to have analogous elements to said posterior surface (Fig. 5B shows that the anterior surface has a central zone, a connecting zone, and a peripheral zone) and said

analogous elements of the anterior and posterior surfaces are equally spaced from each other (Fig. 5B shows that the lens has constant thickness in all the zones).

20. Claims 1, 2, 4-6, 9, 11, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodford (4,297,008). In regard to claim 1, Woodford discloses a corneal contact lens (70 in Fig. 4b) comprising a central zone (optical zone, col. 4, lines 16-17) having a posterior surface curvature (Fig. 4b), a connecting zone (the aspheric curve beginning at the optical periphery of the optical zone and continuing to a flatter portion, col. 4, lines 16-18) having a posterior surface (Fig. 4b) and provided adjacent and concentric to said central zone (Fig. 4b and col. 4, lines 51-53: it is generated by rotation of tool 60), said connecting zone having a shape defined as a sigmoidal curve (working surface 66 of tool 60 has an S-shape: col. 4, lines 64-68), and at least one peripheral zone (the flatter portion of the aspheric curve near the edge of the lens, corresponding to the bevel labeled 16 in Fig. 1, in which only the posterior surface is beveled) having a posterior surface (Fig. 4b) and provided adjacent and concentric to said connecting zone (Fig. 4b).

21. In regard to claim 2, in the Woodford corneal contact lens, the curvature of the central zone is spherical (col. 1, lines 30-32 and col. 4, lines 15-17: the disclosure that an aspheric curve begins at the optical periphery of the optical zone shows that the central zone, within the periphery, is spherical).

22. In regard to claim 4, in the Woodford corneal contact lens, the curvature of the central zone is aspherical (col. 4, lines 15-17: the central zone can be labeled differently than it is labeled for claim 2, so as to include the optical periphery of the optical zone, which is disclosed to be aspheric).

23. In regard to claim 5, in the Woodford corneal contact lens, the curvature of the central zone comprises a combination of annular spherical and aspherical zones (col. 4, lines 15-17; the optical zone is spherical, which can be described as an annular spherical zone with a spherical center of the same curvature, and the optical periphery is aspheric and annular, as disclosed in Fig. 4b with col. 4, lines 51-53).

24. In regard to claim 6, in the Woodford corneal contact lens, the curvature of the central zone comprises a combination of spherical and aspherical zones (see the rejection of claim 5 because claim 6 has no additional limitation).

25. In regard to claim 9, in the Woodford corneal contact lens, the meridional profile of the connecting zone is shaped to match the slopes of the central zone and the at least one peripheral zone on adjacent sides (Fig. 4b shows that at the inner and outer ends of the connecting zone, the slopes match the slopes of the central and peripheral zones).

26. In regard to claim 11, in the Woodford corneal contact lens, the junctions between the connecting zone to the central zone and the at least one peripheral zone require substantially no

polishing or blending (Figs. 4b and 4c, which shows how the curve of tool 60 is generated, and col. 2, lines 31-41 and col. 3, lines 40-45; furthermore, although the manufacturing procedure can be labeled polishing, the resultant, finished contact lens does not require polishing).

27. In regard to claim 19, in the Woodford corneal contact lens, the anterior surface of said lens is comprised of contiguous spherical surfaces (the lens in Fig. 1 has the same features for the posterior surface as lens Fig. 4b and the anterior surface is a spherical surface, which can be divided into zones corresponding to those of the posterior surface so that the anterior surface in Fig. 1 is comprised of a central spherical surface and two annular spherical surfaces).

28. In regard to claim 21, in the Woodford corneal contact lens, the posterior curve of said central zone in combination with the anterior surface curve will yield a desired optical power in said contact lens (col. 4, lines 17: the term "optical zone" shows that the central zone provides desired optical power; a lens provides optical power through the combination of the posterior and anterior surface curves).

29. Claims 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Siviglia (4,787,732, cited in applicants' IDS, paper #4). In regard to claim 25, Siviglia discloses (Fig. 3) a contact lens comprising: a central zone (20) having a posterior surface with a curvature (col. 4, lines 16-18); a connecting zone (the elbow region between central zone 20 and peripheral zone 22) having a posterior surface (Fig. 3) provided adjacent and concentric to said central zone (Fig. 2, where the zone is located at the line between zones 20 and 22, and Fig. 3), and at least one

peripheral zone (22) having a posterior surface provided adjacent and concentric to said connecting zone (Figs. 2 and 3), said peripheral zone being integral with said connecting zone (Fig. 3) and being formed as a truncated conoid over at least a substantial portion thereof (Fig. 3 and col. 5, lines 18-23).

30. In regard to claim 27, Siviglia discloses a contact lens that has the parameters of connecting zone depth (the short axial length of the elbow region) and peripheral zone angle (the angle of the conical surface, or conoid, with the optical axis), which can be obtained by various methods (this product-by-process claim does not imply any structural limitations beyond those of claim 25).

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

32. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over El Hage in view of Harris (5,270,051). El Hage discloses a corneal contact lens that meets the limitations of claim 1, as explained above. However, El Hage does not disclose that the curvature of the central zone is toric. Harris discloses a corneal contact lens in which the curvature of the central zone is toric (col. 11, lines 53-60 and Fig. 4C). Furthermore, Harris teaches that the toric curvature is useful for correcting astigmatism through orthokeratology. Therefore, it would have been obvious to

one of ordinary skill in the art to make the curvature of the central zone of the El Hage corneal contact lens toric, as disclosed by Harris, because such toric curvature can be used to correct astigmatism.

33. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over El Hage in view of Lieberman et al. (5,953,098). El Hage discloses a corneal contact lens that meets the limitations of claim 1, as explained above. However, El Hage does not disclose that different meridional surface profiles for each of the zones are designed at different angles of rotation about the lens central axis. Lieberman discloses a corneal contact lens, which has central, connecting, and peripheral zones (Figs. 7A and 7B), in which different meridional surface profiles for each of the zones are designed at different angles of rotation about the lens central axis (col. 7, line 46, to col. 8, line 9, and col. 9, lines 22-50). Furthermore, Lieberman teaches that such a design provides a better-fitting lens (col. 2, lines 58-63, and col. 9, lines 25-27) and can be used for orthokeratology (col. 4, lines 10-16). Therefore, it would have been obvious to one of ordinary skill in the art to provide different meridional surface profiles for each of the zones at different angles of rotation about the lens central axis, as disclosed by Lieberman, because such a design would provide a better-fitting lens that can be used for orthokeratology, as taught by Lieberman.

Allowable Subject Matter

34. Claims 7, 8, 13, 14, 17, 18, 23, 26, and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims (claim 26 also requires correction of informalities).

35. The following is a statement of reasons for the indication of allowable subject matter: The prior art taken either singularly or in combination fails to anticipate or fairly suggest the limitations of claims 7, 8, 13, 14, 17, 18, 23, 26, and 28, in such a manner that a rejection under 35 U.S.C. 102 or 103 would be proper.

36. The prior art fails to teach a combination of all the features in claim 7. For example, these features include the detailed structure recited in claim 1 and also the limitation that the central zone is designed to correct presbyopia without contacting the cornea. Although El Hage discloses such a lens for correcting hyperopia (which is the main problem in presbyopia), the lens does not have a sigmoid-shaped connecting zone.

37. The prior art fails to teach a combination of all the features in claim 8. For example, these features include the detailed structure recited in claim 1 and also the limitation that the central zone is designed to correct presbyopia by reshaping the cornea.

38. The prior art fails to teach a combination of all the features in claim 13. For example, these features include the detailed structure recited in claim 1 and also the limitation that the peripheral zone is formed as a truncated conoid.

39. The prior art fails to teach a combination of all the features in claim 14. For example, these features include the detailed structure recited in claim 1 and also the limitation that the peripheral zone is formed as a truncated conoid.

40. The prior art fails to teach a combination of all the features in claim 17. For example, these features include the detailed structure recited in claim 1 and also the detailed structure of the peripheral zone. Neither El Hage nor Woodford have that detailed structure.

41. Claim 18 depends on claim 17 and therefore has allowable subject matter as well.

42. The prior art fails to teach a combination of all the features in claim 23. For example, these features include the detailed structure recited in claim 1 and also the limitation that the analogous elements of the anterior and posterior surfaces are unequally spaced from each other. Although Woodford (Fig. 1) discloses a lens in which the anterior and posterior surfaces are unequally spaced, the anterior surface does not have connecting and peripheral zones analogous to those of the posterior surface.

43. The prior art fails to teach a combination of all the features in claim 26. For example, these features include the detailed structure recited in claim 25 and also the further detailed structure of the peripheral zone, such as the shape of a quadrant of an ellipse, as explained in the current specification and Figure 7.

44. The prior art fails to teach a combination of all the features in claim 28. For example, these features include the detailed structure recited in claim 25 and also the limitation that the lens has a plurality of visible concentric rings. Although some prior art references disclose concentric rings formed on contact lenses to improve depth of field or to provide multifocal vision, or simply to form separate zones, those references do not disclose that the rings are visible.

Conclusion

45. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Barsky (6,241,355) provides an example of a connecting zone with a shape that is similar to a sigmoid curve (e.g. the zone labeled 55 of the upper curve in Figure 20(iv)). However, the shape is missing the upper bulge of the sigmoid curve (or a lower bulge).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Raizen whose telephone number is (703) 305-7940. The examiner can normally be reached on Monday-Friday, from 8:30 a.m. to 5 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Y. Epps can be reached on (703) 308-4883. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9318 for regular communications and (703) 872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

dar
August 9, 2003

Scott J. Sugarman
Primary Examiner